## EXHIBIT 8

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Chicago, IL

May 6, 2009

		Page :
UNITED STATES DI	STRICT COURT	
DISTRICT OF MAS	SACHUSETTS	
IN RE: PHARMACEUTICAL	)	
INDUSTRY AVERAGE WHOLESALE	) MDL No. 1456	
PRICE LITIGATION	)	
	) Master File	
	) No. 01-CV-12257-PBS	
HIS DOCUMENT RELATES TO:	)	
	) Subcategory	
•	) No. 06-CV-11337-PBS	
United States of America,	)	
ex rel. Ven-A-Care of the	)	
Florida Keys, Inc., v.	)	
Abbott Laboratories, Inc.,	)	
CIVIL ACTION NO. 06-11337-1	PBS) VOLUME II	
Videotaped Deposi	tion of JAMES W.	
HUGHES, Ph.D., at 77 West W	Wacker Drive, 35th	
Floor, Chicago, Illinois,	commencing at the hour	
of 9:09 a.m. on Wednesday,	May 6, 2009.	

Henderson Legal Services, Inc.

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1 PROCEEDINGS 2

THE VIDEOGRAPHER: Today's date is May 6, 2009. We are on the record at 9:09 a.m.

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JAMES W. HUGHES,

having been previously duly sworn, was examined and testified further as follows:

8 9 10

**EXAMINATION** (Continuing)

- BY MR. LAVINE: 11
- 12 Q. Welcome back, Dr. Hughes.
- A. Thank you. 13
- 14 Q. I just wanted to ask some follow-up 15
- questions about some of your points that you made 16 regarding Dr. Duggan's analysis of the Medicare
- arrays. 17

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- 18 A. Yes.
- 19 Q. And let me just go through the points.
- I think I might be able to ask one question about 20
- all of them. If we need to separate them out. 21
- just let me know.

correct Abbott NDCs were in every array.

2 A. Okay. So that is the point that he

looked to find a price that matched an Abbott

price but doesn't offer, doesn't know with any

degree of certainty that it is in fact the Abbott 5

price, that there was not some other drug, some 6

7 other NDC, that was either in the array

8 legitimately or in the array by mistake that could

9 have that price.

> He said that he had, in his rebuttal he says that he had checked, but, again, it's not clear to me exactly what he had checked.

So as to the exact, I'm sorry, 13

scientific methodology? 14 15

O. Yes.

16 A. Okay. So I mean he's forming, in effect

he's forming a hypothesis, and the hypothesis is 17

that \$10.16 whenever I see that, that's always an 18

Abbott price. 19

20 Again, the idea is that it's an

assumption on his part. There's no scientific 21

22 basis on his part for assuming that every time you

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You said that he hasn't shown the correct Abbott NDCs were in each array. He hasn't shown that Abbott's price moved the median.

He hasn't shown all the arrays to be. well, I have the word "identical," but similar enough within the sample or the extrapolation.

There's no evidence that Abbott was the only manufacturer whose AWP was higher than the actual average selling price. And that he hasn't shown that a hundred percent of the sales of the products under that J-Code were of Abbott products.

And the question about all of those is what is the underlying scientific methodology that you say Dr. Duggan failed to follow with respect to each of those issues?

A. Why don't you give them to me one at a 17 time, and then we'll run through them because I 18 understand it forms a single question but it 19 20 doesn't really form a single answer.

Q. Okay. Fair enough. 21

So first, that he hasn't shown the

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look at a Medicare array and see \$10.16, there's 2 no scientific principle, no scientific

3 methodology, that says oh, well, that must be an

Abbott price.

5 So, again, when one is making an assumption, and as I said before, I'm not against 6 assumptions, I'm not against all assumptions, but 7 you need to provide, you need to provide a basis 8 in the evidentiary record or some sort of basis, 9 economic theory if you like, that if there's some 10 economic law that says \$10.16 is a price that is 11 reserved for Abbott NDCs -- I'm being facetious 12 but you understand what I'm saying -- that he

13 provides no such basis to support that assumption 14

that he's making. 15

Again, the evidence that he does have 16 17 given that there's no set methodology for forming arrays, there's no set methodology for deciding 18

19 whose products are in the arrays, which products

20 are in the arrays, products get into arrays by

mistake, products of the wrong dosage, products of 21

22 the wrong type, get into the arrays.

3 (Pages 302 to 305)

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- put them out there. And then it's up to the
- 2 reader to decide, and this is true in the economic
- 3 literature as I understand it, you put your
- 4 assumptions forward because sometimes you have to
- 5 make them in order to move the analysis forward,
- 6 and then it's up to the reader, it's up to the
- 7 journal editor, it's up to referees, if the paper
- 8 is published it's up to the people who read it to
- 9 decide whether they think that assumption is well
- 10 founded.
- There's plenty of examples of say
- 12 journal articles where a researcher will find a
- 13 certain result, you know, particularly in economic
- 14 theory. But the result may depend on an
- 15 assumption that nobody really believes in.
- So that piece of work may go forward,
- 17 may even be published, but it doesn't have much
- 18 impact because the consensus of the readers is
- 19 that that assumption just doesn't make any sense
- 20 under the circumstances.
- 21 BY MR. LAVINE:

assumptions?

understanding.

under the circumstances.

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Q. So when Dr. Duggan in his analysis fails

of not being allowed to make unfounded

arrays, that fails to meet a standard in economics

A. State your assumptions and state your

foundation for the assumptions, neither of which

One of the critiques is that Dr. Duggan

hasn't shown the correct NDCs were in the array.

and the standard that he's failing to meet is the

assumptions need to be stated, and he's failed to

A. The assumptions need to be stated, and

they need to be supported. You need to say here's

I mean if somebody does an economic

requirement that in economic analysis your

why I'm making this assumption.

Dr. Duggan does, that's my criticism, all right.

Then it's up to readers to decide

whether or not that's a reasonable assumption

Q. I just want to make sure I'm

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- 1 analysis that as one of the assumptions that their
- 2 analysis is based on is that demand curves don't
- 3 really slope downward but demand curves slope
- 4 upward, first of all, that assumption needs to be
- 5 stated.

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- 6 Second of all, the researcher needs to
- 7 put a reason why contrary to everything else
- 8 everybody knows, everybody believes about demand
- 9 curves, this person is saying that they slope
- 10 upwards. And then you put the work out there and
- 11 people, readers, will choose to believe or not
- 12 believe your work based on whether they believe or
- 13 don't believe that assumption.
- Q. All right. So when Dr. Duggan fails to
- show the correct Abbott NDCs were in the array,
- 16 he's failed to state his assumption and he's
- 17 failed to support his assumption?
  - MR. BERLIN: Objection, form.
- THE WITNESS: Well, yes, he's failed to
- 20 state his assumption, he's failed to support his
- 21 assumption.

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But, remember, he's assuming that these

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- to show the correct Abbott NDCs were in the 1 are Abbott NDCs. He's using that to calculate his
  - damage calculation, he's using it to calculate his
  - 3 damages for that carrier for that period. He's
  - 4 then attributing a hundred percent of that damage
  - 5 to Abbott.
  - 6 It certainly seems well within the
  - 7 expectations of best practices in economics that
  - 8 you provide some basis for the belief that just
  - 9 because I see \$10.16 that that is representative
  - 10 of an Abbott NDC and not representative of
  - 11 something that's in there either intentionally or
  - 12 by mistake. And he fails to do that.
  - 13 BY MR. LAVINE:
  - Q. Where would I go to see an objective
  - 15 description of those requirements you just
  - 16 described?
  - MR. BERLIN: Objection, form.
  - THE WITNESS: Could you read back my
  - 19 response, please, my last response.
  - 20 (The record was read back as
  - 21 requested.)
  - THE WITNESS: As I was saying yesterday,

5 (Pages 310 to 313)

do that.

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1 when one's performing, when one uses 2 extrapolation, one's by definition introducing 3 error into the analysis because you are not using 4 actual data, you're extrapolating from one

So statistically speaking, you're going to be introducing error because you're creating data, you're not using actual data.

9 That error from extrapolation is going 10 to be compounded if where you're extrapolating to. 11 the data that you're extrapolating to, in this 12 case -- excuse me. Let me try that again.

13 The data that you're using for the 14 extrapolation, in this case the purported Abbott 15 NDC that he says that he sees in arrays, if that's 16 not accurate he's introduced yet another degree of 17 error into his extrapolations.

MR. LAVINE: I object, move to strike as 18 nonresponsive. 19

20 BY MR. LAVINE:

situation into another.

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Q. My question was is there an objective 21 22 source, a peer-reviewed material, a learned

accuracy, he offers no confidence intervals, he offers no test of statistical significance.

He offers nothing of the sort, nothing of the type of thing that it would be standard practice, and I'm sure is contained in every bit of Dr. Duggan's published econometric work, the measures of accuracy and the measures of goodness of fit and all of these other measures that economists and statisticians typically use to measure the accuracy of somebody's estimation.

11 We have extrapolations with reasons to believe that there's been error introduced to 12 these extrapolations.

First of all, from the very act of extrapolation. And, secondly, because of the lack of certainty or the lack of evidence offered that he actually has the correct NDCs in the array.

There are lots of things in statistics books and lots of things in econometrics books that talk to how regression analysis, which is not what Dr. Duggan has done here, but how economic analysis generally is affected when you think you

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treatise, anything of the sort, that would 2

articulate the standards that you're describing so

3 that we could look it up and determine whether or not Professor Duggan was meeting those standards? 4

A. Well, one could look to an econometrics book at the problems that are introduced into estimation when you have problems, so-called errors in variable.

Q. What would the rule say?

10 A. The rule would say is that when your 11 independent variables are mismeasured, your 12 estimates lose precision.

Q. So is that the standard that we should use to judge whether or not Dr. Duggan handled 14 things appropriately with respect to showing the 15 Abbott NDCs were in the array? 16

MR. BERLIN: Objection, form.

18 THE WITNESS: My objection to Dr.

Duggan's analysis is we have to rely on his word 19

20 for how accurate these extrapolations are.

21 He's not performing anywhere in his 22 report, he performs no statistical test of

have one variable and you actually have something 1 2 else.

And there are ways for approaching those problems, there are ways for handling those problems.

When one is faced with such a problem in an econometric analysis, one acknowledges the fact and then either takes corrective action or adjusts their standard, does adjustments to standard errors and does adjustments to their confidence 11 intervals to take those things into account.

None of that's done here. We have no 12 13 reason to accept the accuracy of Dr. Duggan's extrapolations but Dr. Duggan's word that these 14 are all Abbott NDCs. 15

And given, you know, he's a well-16 published empirical economist, just giving in the 17 academic world, in academic research, just giving 18 the editor, or giving reviewers your word that 19

these are really good estimates would not fly. 20 That's my objection, is that this is not 21

22 meeting any sort of standard of accuracy that's

6 (Pages 314 to 317)

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Eli Lilly was the innovator. That's right. I'm sorry.

- Q. Are you thinking perhaps erythromycin?
  - A. Correct.

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- 5 O. Abbott was the branded innovator.
- 6 A. Was the branded innovator, yes.
- 7 Q. As an economist, how much should, in
- 8 your but-for world, how much should the states
- 9 have increased their dispensing fees for the drugs10 in question when Abbott reduced its price reports
- 11 in the 2000, 2001 timeframe?
- MR. BERLIN: Objection, form.
- THE WITNESS: I've not done calculation
- 14 or the surveys or anything that would need to be
- 15 done to ascertain that. So I don't know.
- 16 BY MR. BREEN:
- Q. But it's your opinion they should have; 18 right?
- 19 A. It's my opinion that pharmacies would
- 20 have found the reimbursements in line with Dr.
- 21 Duggan's reimbursements to be unremunerative.
- Q. My question is how much should they have

goes through.

The DRA didn't end up being implemented as yet, but yet the states were undergoing precisely those reviews and at least in the case

of Texas were making such determinations.

Q. Okay. Well, when it came to IV
 pharmacy, how many states that had already
 increased their dispensing fees conduct a review

9 and said we have to increase them more?

- A. I don't know the answer to that.
- Q. So let me get this straight. Let's assume that the dispensing fees for a particular state are adequate, according to your whatever you
- would decide would be adequate, we'll make you the
  Zarr, the Medicaid Zarr, and dispensing fees are
- 16 adequate at a certain point in time.

Abbott decides though that they're going to increase their price reports a thousand percent. So that their AWP is a thousand percent higher than the actual selling price generally and

higher than the actual selling price generally ar currently paid in the marketplace for the drug.

A. A thousand percent, but it may be \$2 or

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increased their dispensing fee for the Abbott

- 2 drugs when Abbott reported lower prices in the
- 3 2000, 2001 timeframe, according to your opinion?
  - MR. BERLIN: Same objection.
- 5 THE WITNESS: Again, I don't have a
- 6 number. I have not done the calculation.

7 But we have seen what the administration

- 8 fees were increased by under the MMA, which was a
- 9 substantial amount.
- 10 BY MR. BREEN:

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- Q. Well, let's talk about Medicaid now.
- You've already said that you're aware
- 13 that the states were already increasing
- 14 administration fees. You just don't know when or
- 15 where or who.
- So do you even know if it was necessary
- 17 to increase them any more in the post-2000
- 18 timeframe in connection with the Abbott drugs?
- A. Well, again, under Medicaid and under
- 20 the DRA, states were supposed to review them and
- 21 states did undertake the review, Texas undertook a
- 22 review that here's what we need to do if the DRA

\$3 that we're actually talking about.

- Q. Well, maybe it's \$2 or \$3, but when you do infusion pharmacy how many, don't you have to use these bags of solutions every time you give a prescription?
- A. It's my understanding it's close to that at least, yes.
  - Q. So it's \$2 to \$3 on the bag and then whatever it is on the actual drug that goes in the prescription; correct?

MR. BERLIN: Objection, form.

THE WITNESS: The drug that goes in the

13 prescription? I'm not sure what --

- 14 BY MR. BREEN:
  - Q. Let's say it's vancomycin.
- 16 A. Okay.
- Q. Let's say that the inflated
- 18 reimbursement is \$10 on the bag of fluids and \$100
- 19 on the vancomycin.
- 20 MR. BERLIN: Objection, form.
- 21 BY MR. BREEN:
- Q. Every time the vancomycin is

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administered, you need another bag of fluids;correct?

- 3 A. Correct.
- Q. Anyway, so let's say that Abbott decidesto report higher prices that results in a higher
- 6 AWP one year, and then the next year it decides
- 7 no, we're going to lower them, we're going to
- 8 report prices that are consistent with our market.

9 Is it your testimony that that, those 10 two decisions by Abbott to raise it and then lower

11 it again, will somehow cause the Medicaid programs

12 to have to pay a higher dispensing fee?

A. I'm not addressing the raising and then lowering, but I was addressing the lowering to levels commensurate with what Dr. Duggan has

proposed.
Q. Well, when you say lowering the levels
commensurate with what Dr. Duggan has proposed, is

- 19 it your opinion that Dr. Duggan's proposal is not
- 20 consistent with the regulation that required
- 21 estimation of acquisition cost based upon prices
- 22 generally and currently paid in the marketplace?

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- case, and in those situations even at current
- 2 levels of EAC the dispensing fees are even more
- 3 inadequate than they are for pills and tablets.
- 4 BY MR. BREEN:
- Q. Okay. So for the vancomycin again on Exhibit 4, your Exhibit 4. Deposition Exhibit 1
- Exhibit 4, your Exhibit 4, Deposition Exhibit 12,forgetting the twenty percent range between an
- 8 actual WAC and an average wholesale price,
- 9 forgetting that range, how much are the states
- 10 going to have to increase dispensing fees on
- vancomycin, Abbott's vancomycin, as a result of
- 12 Abbott reporting prices that are closer to market
- 13 based upon the studies you have reviewed?
  - A. There was not numbers given in the studies that I reviewed.
- Q. Okay. So my question then is if you're going to criticize Dr. Duggan's claim-by-claim
- 18 drug-by-drug NDC-by-NDC specific damages model,
- 19 then can you point to any specific quantitative
- 20 evidence that an economist would utilize to
- 21 determine how much in your alternate world the
- 22 Medicaid programs are going to, according to you,

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A. I haven't reached an opinion on that.

But I am saying that the total

reimbursement is being reduced to a level thatthreatens the access by Medicaid patients to

- 5 healthcare services to approximately the same
- degree that those services are available tononMedicaid patients.
- 8 Q. That's your opinion?
- 9 A. Yes.

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- Q. But you don't have one scintilla of
- 11 quantitative evidence that you've actually
- 12 developed yourself or reviewed that somebody else
- 13 did relating to the drugs at issue in this case
- 14 that supports that opinion; do you?
  - MR. BERLIN: Objection, form.
- THE WITNESS: Again, I disagree.
  For example, the Myers & Stauffer
- For example, the Myers & Stauffer reports speak to the inadequacy at existing levels
- 19 of EAC in the dispensing fees for pills and
- 20 tablets and then go on to say that this problem is
- 21 going to be worse for infusion drugs, which are
- 22 the drugs like the drugs that are at issue in this

increasing dispensing fees on vancomycin based upon Abbott's reporting lower prices?

A. Again, to come to the opinions that I came to in my report, I relied on the testimony

- 5 and the evidence in the reports that the people
- who know the state Medicaid systems better than I do, better than Dr. Duggan does, better than you
- 8 do, the people who are actually having to make the
- 9 rules day in and day out, had stated that if you
- 10 have drastic reductions, or even not drastic
- reductions, if you had significant substantial reductions in ingredient cost, you will also have
- to worry about what's happening on the dispensing
- fee side, lest you have problems with access.And your expert. Dr. Schondelmeyer, s

And your expert, Dr. Schondelmeyer, says exactly the same thing in his California report.

- 17 That reductions in the ingredient cost, modest though they were compared to Dr. Duggan's
- 19 reduction in ingredient costs, the reductions in
- 20 ingredient costs in California were going to
- 21 require increases in dispensing fees, or else, I

believe in Dr. Schondelmeyer's words, you were

69 (Pages 566 to 569)